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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/855,542 | 05/16/2001 | Rajesh Manchanda | BERLX-100 | 9728 |

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| EXAMINER |
|---|
| WELLS, LAUREN Q |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1617 | |

DATE MAILED: 11/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Applicati n No. | Applicant(s) | |
|---|---|---|---|
| | 09/855,542 | MANCHANDA, RAJESH | |
| | Examiner | Art Unit | |
| | Lauren Q Wells | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *06 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *7,10,17,20 and 23-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,9,11-16,18,19,21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Pri rity under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

Claims 1-31 are pending. Claims 7, 10, 17, 20 and 23-31 are withdrawn from consideration, as they are directed to non-elected subject matter.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-22, drawn to a composition, classified in class 424, subclass 1.11.

II. Claims 23-31, drawn to kits, classified in class 206, subclass 569.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, a composition and a kit are not usable together. A kit functions to hold something, while a composition functions to be used to affect something.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with John Sopp on 10/2/02 a provisional election was made with without traverse to prosecute the invention of Group I, claims 1-22. Affirmation of this election must be made by applicant in replying to this Office action.

Applicant's election without traverse of Tc-99m as the radionuclide, depreotide as the targeting agent, and KI as the source of iodide ions in Paper No. 4 is acknowledged.

The Examiner searched a composition comprising Tc-99m, depreotide, and iodide ions, but no art was found to anticipate or render the composition obvious. Thus, claims directed to these species would be allowable. The Examiner extended her search to a composition comprising I-125, depreotide, and iodide ions. The search was not extended beyond this because prior art was found to render the species obvious.

***Claim Rejections - 35 USC § 112***

Claims 5 and 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The term "small" in claims 5 and 15 (line 2) is a relative term which renders the claim indefinite. The term "small" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Does small mean 3 carbon atoms? Does it mean 20 carbon atoms? What does it mean?

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 11-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al. (Appl. Radio).

Suzuki et al. teach a composition comprising 3-N-[11C]methylspirerone and potassium iodide. Thus, Suzuki et al. and the instant invention both teach a composition comprising a radionuclide (11C), a peptide targeting agent (3-N-methylspirerone), and alkali metal iodide salt (potassium iodide). See pg. 595.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 8-9 and 11-16, 18-19, 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blum et al. (Chest) in view of Dean (6,214,316) in further view of Coy et al. (5,597,894).

The instant invention is directed to a composition comprising a radionuclide, a targeting agent, and iodide ions, and methods of stabilizing a composition comprising adding iodine ions.

Blum et al. teach 99mTc depreotide for the evaluation of solitary pulmonary nodules. See abstract.

Dean teaches radiotherapeutic and radiodiagnostic reagents comprising somatostatin analogs. 123-I, 125-I, and Tc-99m are disclosed as radionuclides that are useful for radioimaging. 125-I and 131-I are disclosed as radionuclides which are also cytotoxic. Further disclosed is a method of administering the composition to a mammalian body and imaging the body through scintigraphy. See Col. 3, lines 21-59; Col. 10, line 54-Col. 11, line 19.

Coy et al. teach multi-tyrosinated somatostatin analogs. Disclosed is a composition comprising a somatostatin analog and 125I sodium iodide. See abstract; Col. 24, lines 19-34.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the 125-I of Dean for the 99mTc of Blum et al. because a) Dean and Blum et al. are both directed to radioimaging compositions comprising somatostatin analogs; b) Dean et al. teach 125-I and Tc-99m as interchangeable radionuclides for use in radioimaging, and Dean et al. further teach 125-I as having cytotoxic properties in addition to imagining properties; thus, one of skill in the art would be motivated to substitute the Tc-99m of Blum et al. for the 125-I of Dean because of the expectation of achieving a complex that is useful both in radioimaging and as a radiotherapeutic.

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the 125-I of the combined references as the 125-I sodium iodide of Coy et al. because a) the combined references and Coy et al. are both directed to 125-I labeled somatostatin analogs and Coy et al. teach that 125-I can be added to a composition comprising a somatostatin analog in the form of a sodium iodide salt; thus, one of skill in the art would have been motivated to teach the 125-I of the combined references as a sodium iodide salt because Coy et al. that the radioiodination of a somatostatin analog occurs when the analog and a sodium iodide salt are combined.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw

SREENI PADMANABHAN
PRIMARY EXAMINER 10/14/02